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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,233	12/31/2003	Robert L. Martuza	066683-0196	7116

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EXAMINER

WOITACH, JOSEPH T

ART UNIT PAPER NUMBER

1632

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

10/748,233

Applicant(s)

MARTUZA ET AL.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application filed December 31, 2003 is a divisional of 09/625,509, filed July 25, 2000, now US Patent 6,699,468, which is a divisional of 09/004,511, filed January 8, 1998, now US Patent 6,139,834.

Applicants preliminary amendment filed September 8, 2004 has been received and entered. Claims 1-6 have been canceled. Claims 7-18 have been added. Claims 7-18 are pending and currently under examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 10 recites that the HSV is "G207", however it is unclear to the metes and bounds encompassed by this term. G207 is not specifically defined in the present specification, nor is it a readily accepted term of art for HSV. Further, the figures (figure 2 and

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3) would support that there is possible variations encompassed by the disclosure of G207-1 and G207-2, and thus are relative to what one would choose to call a particular vector.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Martuza *et al.* (US Patent 5,85,096 Dec 1996).

The claims encompass a herpes simplex virus whose genome comprises a mutation in the γ 34.5 gene, an expressible gene of interest, and a mutation in the ribonucleotide reductase, and more specifically G207. Martuza *et al.* teach HSV with mutations in one or both of the γ 34.5 genes and a mutation in IPC6 which is the ribonucleotide reductase gene. Martuza *et al.* teaches that the HSV can comprise an expressible gene of interest for use in treating tumor cells (see column 3). The gene of interest can be expressed by using an endogenous HSV promoter or by providing a heterologous promoter.

Claims 7-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Martuza *et al.* of WO 96/00007 (1/1996).

Martuza *et al.* teach HSV with mutations in one or both of the γ 34.5 genes and a mutation in IPC6 which is the ribonucleotide reductase gene(see pages 5-6 and figures 1-2). Martuza *et*

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al. teaches that the HSV can comprise an expressible gene of interest for use in treating tumor cells (pages 5-6).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-29 of copending Application No.

10/788,410. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to the same herpes virus construct. In each case the claims as a whole set forth a herpes virus comprising an alteration in γ 34.5, a heterologous gene of interest and an alteration in the ribonucleotide reductase gene.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 7-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35-39, 43--46 of copending Application No. 11/097,391. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to the same herpes virus construct. In each case the claims as a whole set forth a herpes virus comprising an alteration in γ 34.5, a heterologous gene of interest and an alteration in the ribonucleotide reductase gene. For example claim 10 and claim 39 both set forth that the HSV is G207.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

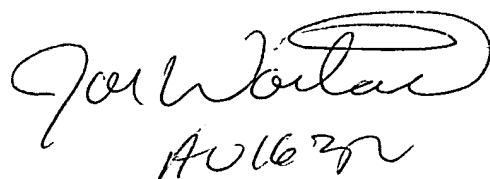
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach



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